

### **REMARKS**

By this Amendment, claims 45, 49, 50, 53, 54, 57, 62, 65, 66, 69, 74, 77, 78, 86, 89, and 90 are amended. The amendments to the claims that are made to address issues raised in the Office Action are discussed in detail in the remarks that follow.

Other amendments, however, have been made that are not in response to issues raised in the Office Action or to the patentability of the claims. Briefly, these amendments and the reasons for them are as follows. First, claim 45 is amended to recite "said photosensitizer being associated with a specific binding pair member that is capable of binding directly or indirectly to the analyte or competing with the analyte for a specific binding pair member" to focus the claims on a preferred embodiment of the invention, and not in response to any rejection set forth in the Office Action. Accordingly, this amendment is not made for the purposes of patentability. Second, claim 45 is amended to recite that the specific binding pair member "is capable of binding directly or indirectly to the analyte". This amendment is made solely to recite an inherent characteristic of the specific binding pair members, and is not made in response to any rejection. Third, claim 49 is amended solely to correct a mistake in grammar that did not render the claim unclear or vague, and thus is not made for the purposes of patentability.

For the reasons stated below, Applicants submit that the claims are in condition for allowance, and request that the Examiner review this application in view of the amendments to the claims and the following comments, reconsider and withdraw the outstanding rejections, and permit this application to issue as a U.S. patent in due course.

I. *Information Disclosure Statement and PTO-1449*

The Office states that the USPTO file does not contain copies of references C15 and C15 from the PTO-1449. (Office Action at paragraph 1.) Attached to this Amendment are additional copies of these two references, along with a copy of the originally filed IDS and PTO-1449, which were filed to disclose these two references. Applicants request that the Examiner acknowledge receipt and consideration of these two references by initialing the attached copy of the PTO-1449 at the appropriate lines, and returning the PTO-1449 to Applicants.

II. *Objections To Claims*

The Office objects to claim 57 for reciting " AR' " rather than " Ar' ". (Office Action at paragraph 2.) By this Amendment, claim 57 is amended to correct this obvious typographical error. Correction of this typographical error does not alter the scope or content of the claim. Thus, it does not limit the scope of the claim. In view of this amendment, Applicants request that the Office withdraw this objection.

III. *Rejections Under 35 U.S.C. § 112, first paragraph*

The Office rejects claims 45-64, 66-76, 78-88, and 90-92 under 35 U.S.C. § 112, first paragraph, as lacking written description support in the specification for the compound in claim 45, part ii), and for the compound in the method of claim 69. (Office Action at paragraph 6.) Specifically, the Office asserts that the specification requires that the compound have a structure as depicted on pages 6, 7, and 37, and that the

assay requires the use of particles and a binding pair member that is specific for the analyte of interest. Applicants traverse this rejection.

In a first aspect, the Office asserts that the specification only describes compounds having a structure as depicted on pages 6, 7, and 37, and thus the claims must be limited to these structures to comply with the written description requirement. While not necessarily agreeing with this assertion, Applicants submit that the language of claim 45 (the only independent claim in the application) specifically describes the three structures depicted at the top of page 37. In addition, claim 69 recites, essentially verbatim, the written description bridging page 37, line 15 and page 38, line 13. The Examples show several syntheses of compounds encompassed by the claims, and use of those compounds in luminescence trials. Thus, even accepting the Office's characterization of what is required (a characterization with which Applicants do not necessarily agree), the claims satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Accordingly, Applicants request that the Office reconsider and withdraw this aspect of the rejection.

In a second aspect of the rejection, the Office asserts that the description of the methods of the invention requires the use of particles. Applicants submit that this assertion is not accurate. The specification, at page 52, line 32, through page 54, line 28, for example, discloses that the invention encompasses the use of a chemiluminescent compound (a "compound" according to the claims) associated with a specific binding pair member, and a photosensitizer associated with a specific binding pair member. It further states that preferably at least the chemiluminescent compound is incorporated in particles. While it is preferable to incorporate the compound into

particles, it is not necessary. Likewise, while it is preferable to incorporate the compound into particles, it is not necessary to incorporate the photosensitizer. The specification clearly describes (and thus shows possession of) direct linking of a chemiluminescent compound or a photosensitizer and a specific binding pair member at, for example, page 25, line 30, through page 26, line 4, where it is disclosed that functional groups can be introduced on a photosensitizer or chemiluminescent compound to link them to a specific binding pair member or to a particle. In view of the disclosure of the specification, Applicants request that the Office reconsider and withdraw this aspect of the rejection.

In a third aspect of the rejection, the Office asserts that the method requires the use of a binding pair member that is specific for the analyte of interest. Applicants submit that this is an incorrect interpretation of the disclosure of the specification. While the methods of the invention include a specific binding pair member, that substance does not necessarily specifically react with the analyte of interest. That is, as disclosed for example on page 51, line 23, through page 52, line 9, a specific binding pair member may be specific for the analyte of interest (*i.e.*, binds directly) or for some other substance whose presence or concentration can be related back to the presence or concentration of the analyte of interest (*i.e.*, binds indirectly).

By this Amendment, and solely to explicitly recite inherent functions of the specific binding pair members recited in the claims and disclosed in the specification, claim 45 is amended at parts a)2) and a)3) to recite a specific binding pair member that is capable of binding directly or indirectly to the analyte or competing with the analyte for a specific binding pair member. This amendment is not made to address the rejection

under 35 U.S.C. § 112, first paragraph. Rather, it is made solely to recite characteristics of the specific binding pair members recited in the claims. As such, it is not made for patentability purposes and does not limit the scope or content of the claims.

For at least the reasons set forth above, Applicants submit that the claims satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Therefore, Applicants request that the Office reconsider and withdraw the outstanding rejection of claims 45-64, 66-76, 78-88, and 90-92 under 35 U.S.C. § 112, first paragraph.

#### IV. *Rejections Under 35 U.S.C. § 112, second paragraph*

The Office rejects claims 45-92 under 35 U.S.C. § 112, second paragraph, as indefinite. (Office Action at paragraph 7.) In view of the amendments to the claims and the following comments, Applicants submit that all of the reasons for the rejections have been addressed and overcome. Therefore, Applicants request that the Office reconsider and withdraw the rejections.

The Office rejects claim 45 for reciting the term "oxygen group". While not necessarily agreeing with the Office with regard to the definiteness and clarity of this term, to expedite allowance of the application, by this Amendment, claim 45 is amended to eliminate the word "group". Applicants submit that claim 45, which now recites "oxygen" rather than "oxygen group" would be clear and definite to one of skill in the art.

The Office rejects claim 45 for failing to recite a step that relates the method steps to the presence or absence of an analyte. By this Amendment, claim 45 is amended to recite that the step of detecting relates the amount of luminescence to the amount of analyte in the medium. This amendment does not alter the scope or content

of the claim, but merely recites an inherent result obtained by practicing the recited method. Thus, the amendment does not limit the scope of the claim. Support for the amendment comes from the specification at page 7, lines 7-19, for example.

The Office rejects claims 53, 54, 65, 66, 77, and 89 for failing to recite what the specific binding pair member binds to, and for reciting multiple specific binding pair members and particles. The Office also asserts that claim 50 permits only a single particulate material. As discussed above, by this Amendment, claim 45 is amended to recite two specific binding pair members, and that the specific binding pair members bind the analyte directly or indirectly. Claims 53, 54, 65, 66, 77, 78, 89, and 90 are amended to maintain proper claim language in view of these amendments. The amendments to claims 53, 54, 65, 66, 77, 78, 89, and 90 do not change the scope or content of the claims, and thus do not limit the scope of the claims. Further, by this Amendment, claim 50 (and claims 62, 74, and 86) is amended to more clearly recite that at least two particulate materials are present. The amendment of claim 50 (and claims 62, 74, and 86) does not alter the scope or content of the claim; thus, the amendment does not limit the scope of the claim. Applicant believes the amendments to these claims address the Office's concern regarding claim 53.

The Office rejects claim 69 for reciting "organic radical" and "taken together to form a ring". By this Amendment, claim 69 is amended to more clearly recite what is encompassed by the wavy lines in the structure recited in that claim. The amendments to claim 69 do not alter the scope or content of that claim. Therefore, they do not limit the scope of the claim.

The Office rejects claim 81, asserting that it is not clear what the difference is between an alkyl and an alkyl radical. Applicants submit that the difference between the two terms is presented in the specification at page 19, lines 1-14, for example. In view of the disclosure of the specification, Applicants submit that one of skill in the art would know what each of these terms means.

In view of the amendments to the claims and the comments above, Applicants submit that all of the issues raised in the Office Action under 35 U.S.C. § 112, second paragraph, have been addressed and overcome. Therefore, Applicants request that the Office reconsider and withdraw the rejections under this statute and paragraph.

V. *Double Patenting*

The Office rejects claims 45-92 under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 6,180,354. (Office Action at paragraph 9.) While not necessarily agreeing with the Office on this issue, to expedite allowance of the application, attached to this Amendment is a Terminal Disclaimer, executed by an authorized agent of the assignee, disclaiming any terminal portion of a patent issuing from this application beyond the patent term of U.S. Patent No. 6,180,354. In view of the attached Terminal Disclaimer, Applicants request that the Office reconsider and withdraw the obviousness-type double patenting rejection.

VI. *Conclusion*

Applicants submit that this application is in condition for allowance. Accordingly, Applicants request that the Office reconsider and withdraw the outstanding objection and rejections, and permit this application to issue as a U.S. patent in due course. If the Office believes anything further is necessary to place this application in even better condition for allowance, Applicants request that their undersigned representative be contacted at the telephone number listed below.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: November 29, 2004  
(November 28, being a Sunday)

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